

(d) The Regional Food and Drug Directors, District Directors, and the Director, St. Louis Branch, are authorized to exercise all of the functions of the Commissioner of Food and Drugs under section 362 of the PHSA that refers to the prohibition of the introduction of foods, drugs, devices, cosmetics, and electronic products and other items or products regulated by the Food and Drug Administration into the United States when it is determined that it is required in the interest of public health, and such functions relate to the law enforcement functions of the Food and Drug Administration.

(e) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs pertaining to exportation of medical devices under section 801(e) of the FDCA:

(1) For medical devices assigned to their respective organization:

(i) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH).

(ii) The Director and Deputy Director, Office of Compliance and Surveillance, CDRH.

(iii) The Director and Deputy Director, Division of Compliance Operations, Office of Compliance and Surveillance, CDRH.

(iv) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(v) The Director and Deputy Director, Office of Compliance, CBER.

(2) Regional Food and Drug Directors.

(3) District Directors.

(4) The Director, St. Louis Branch.

(f) The following officials are authorized to perform the functions of the Commissioner of Food and Drugs, for drugs under their jurisdiction, pertaining to authorizing the reimportation of prescription drugs under section 801(d)(2) of the FDCA for emergency medical care:

(1) The Director, Center for Biologics Evaluation and Research (CBER) and the Director, Office of Compliance, CBER.

(2) The Director, Center for Drug Evaluation and Research (CDER) and

the Director, Office of Compliance, CDER.

[48 FR 8441, Mar. 1, 1983, as amended at 48 FR 56946, Dec. 27, 1983; 49 FR 572, Jan. 5, 1984; 49 FR 14933, Apr. 16, 1984; 51 FR 32452, Sept. 12, 1986; 54 FR 6518, Feb. 13, 1989; 54 FR 8317, Feb. 28, 1989; 54 FR 9034, Mar. 3, 1989; 55 FR 47053, Nov. 9, 1990; 57 FR 40318, Sept. 3, 1992]

§ 5.46 Manufacturer's resident import agents.

The Director and Deputy Director, Center for Devices and Radiological Health (CDRH) and the Director and Deputy Director, Office of Compliance and Surveillance, CDRH, are authorized to reject manufacturer's designations of import agents under § 1005.25(b) of this chapter.

[55 FR 47053, Nov. 9, 1990]

§ 5.47 Detention of adulterated or misbranded medical devices.

The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs pertaining to detention, under section 304(g) of the Federal Food, Drug, and Cosmetic Act and in accordance with § 800.55 of this chapter, of medical devices that may be adulterated or misbranded:

(a) For medical devices assigned to their respective organizations:

(1) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Compliance and Surveillance, CDRH.

(3) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(4) The Director and Deputy Director, Office of Compliance, CBER.

(b) Regional Food and Drug Directors.

(c) District Directors.

(d) The Director, St. Louis Branch.

[48 FR 8442, Mar. 1, 1983, as amended at 48 FR 56947, Dec. 27, 1983; 49 FR 14933, Apr. 16, 1984; 51 FR 32452, Sept. 12, 1986; 54 FR 8317, Feb. 28, 1989; 55 FR 47053, Nov. 9, 1990]

§ 5.49 Authorization to use alternative evidence for determination of the effectiveness of medical devices.

The following officials, for medical devices assigned to their respective